The opinion in support of the decision being entered today was <u>not</u> written for publication and is <u>not</u> binding precedent of the Board.

## UNITED STATES PATENT AND TRADEMARK OFFICE

## BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte MARC ALIZON,
FRANCOISE BARRE SINOUSSI,
PIERRE SONITO,
PIERRE TIOLLAIS,
JEAN-CLAUDE CHERMANN,
LUC MONTAGNIER, and
SIMON WAIN-HOBSON

Appeal No. 2005-0256 Application No. 08/466,921 MAILED

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U.S. PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

ON BRIEF

Before MILLS, GRIMES, and GREEN, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

## REQUEST FOR REHEARING

Appellants request rehearing of the decision entered September 26, 2005. That decision affirmed the rejection of claims 62-73 for lack of adequate written description.

Appellants assert that the previous decision erred in overlooking the broad teachings in the specification. More specifically, Appellants argue that the specification

<sup>&</sup>lt;sup>1</sup> The merits panel that issued the initial decision in this appeal included Administrative Patent Judge William F. Smith, who has since retired from the USPTO. APJ Green has replaced APJ Smith on this panel. See In re Bose Corp., 772 F.2d 866, 227 USPQ 1 (Fed. Cir. 1985).

discloses "cloned DNA sequences hybridizable to genomic RNA and DNA" of HIV-1. See the Request for Rehearing, page 3 (citing the first sentence of the specification). Appellants then point to other portions of the specification that set out specific hybridization conditions: page 9, where the specification teaches hybridization of a fragment of HIV-1 DNA to other HIV-1 DNAs; page 11, where the specification teaches that HIV-1 DNA does not hybridize to the DNA of a different virus (HTLV-II) under low stringency conditions; and page 12, where the specification teaches that HIV-1 DNA does not hybridize with "a number of human endogenous viral genomes under non[-]stringent conditions."

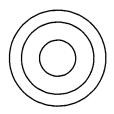
Appellants reason that the hybridization conditions taught on pages 11 and 12 of the specification "were less stringent than the conditions on page 9, and no hybridization of HIV-1 DNA to [other viruses] was detected under these conditions, [so] the skilled artisan would have understood that these were suitable hybridization conditions contemplated by the inventors for use with HIV-1 DNA fragments." Request for Rehearing, page 4. Appellants conclude that "[w]hen these broad teachings of Appellants' specification are taken into consideration, the skilled artisan would have been directed to the claimed hybridization conditions." <u>Id.</u>, page 5.

We have considered Appellants' argument but do not find it persuasive. "The purpose of [the written description] provision is to ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification. See . . . Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1561, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991) ('Adequate description of the invention guards against the inventor's overreaching by

insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation.' (quoting Rengo Co. v. Molins Mach. Co., 657 F.2d 535, 551, 211 USPQ 303, 321 (3d. Cir. 1981))." Reiffin v. Microsoft Corp., 214 F.3d 1342, 1346, 54 USPQ2d 1915, 1917 (Fed. Cir. 2000).

Here, the claims are directed to fragments of HIV DNA that hybridize to genomic HIV DNA under nonstringent conditions, while the specification only discloses HIV DNA fragments that hybridize under more stringent conditions. Stringency of hybridization conditions is a measure of how similar two DNAs must be in order to hybridize. Under high stringency conditions, only DNAs that are substantially identical will hybridize. See Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 967, 63 USPQ2d 1609, 1615 (Fed. Cir. 2002) (all species within a genus of nucleic acids that hybridize under "highly stringent conditions to known sequences" will be structurally similar).

Under low- or non-stringent conditions, by contrast, DNAs will hybridize to each other despite significant differences in structure. See, e.g., page 11 of the specification (HTLV-I and HTLV-II "hybridize between themselves under reasonably stringent conditions" even though they are different viruses). Thus, the group of DNAs that will hybridize to the genomic DNA of HIV-1 under nonstringent conditions is larger than the group of DNAs that will hybridize under more stringent conditions. The relationship between stringency conditions and the number of DNAs that will hybridize under those conditions can be illustrated as follows, where the inner circle represents the most stringent conditions, and the successively larger circles represent low- and non-stringent conditions:



Each of the circles encompasses the DNAs in the smaller circle(s) within it: each DNA that hybridizes to HIV-1 genomic DNA under highly stringent conditions will also hybridize to it under nonstringent conditions, but the reverse is not true. Thus, the genus of DNAs that will hybridize to HIV-1 genomic DNA under the nonstringent conditions recited in claims 62-73 is larger than the genus of DNAs that will hybridize to the same DNA under the conditions described on page 9 of the specification.

The issue in this case is whether the specification's description shows possession of the larger, claimed genus. See Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991): "[T]he applicant must . . . convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed."

One can show possession of a genus of nucleic acids by describing "a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." <u>University of California v. Eli Lilly and Co.</u>, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Besides nucleotide sequence, the species can also be described by reference to deposits or "disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." <u>Enzo</u>, 323 F.3d at 964, 63 USPQ2d at 1613.

Here, Appellants point to the species shown to hybridize under the conditions recited on page 9 of the specification and argue that those species would also be expected to hybridize under less stringent conditions, such as those recited in the claims. The problem with Appellants' argument is that they have pointed to no HIV DNA fragments, described in the specification, that (1) hybridize to HIV genomic DNA under non-stringent conditions and (2) do not hybridize under the stringency conditions set out on the specification's page 9. Appellants have therefore not shown that the specification describes any species encompassed by the claims but not encompassed by the genus of DNAs that hybridize to HIV under the conditions set out on page 9.

That is, all of the species of HIV DNA fragments described in the specification fall into the smallest of the genera discussed above. In terms of the illustration set out above, Appellants are claiming everything encompassed by the largest circle but only pointing to species within the smallest circle for descriptive support. We find that the species relied upon are not representative of the genus claimed. The description provided in the specification does not show possession, at the time of filling, of the genus of HIV DNA fragments defined by claims 62-73.

In summary, we have reconsidered our previous opinion in light of Appellants' request for rehearing but decline to make any changes in the opinion.

## REHEARING DENIED

Administrative Patent Judge

Eric Grimes

Administrative Patent Judge

Lora M. Green

Administrative Patent Judge

) BOARD OF PATENT

**APPEALS AND** 

) INTERFERENCES

EG/jlb

Appeal No. 2005-0256 Application No. 08/466,921

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